PROJECT NARRATIVE:

A. Introduction

Barriers to early identification and intervention for children with Autism Spectrum Disorder (*ASD*) *must be addressed.* Access to evidence-based approaches to diagnosing and treating young children with ASD in community services is limited, particularly for disadvantaged groups (Doreis, et. al., 2006; Sand, et. al. 2005; Zuckerman, et. al., 20013; Fountain, King and Bearman, 2011). Disparities in timely identification of children with autism spectrum disorders (ASD) and subsequent delays in treatment entry are common, with minority children typically not identified until after age eight (Mandell, et. al., 2002; Mandell, et. al., 2005; Mandell, et. al., 2007). Delays in identification and referral lead to delays in accessing the early intervention shown to be critical in improving child outcomes (Dawson, et. al. 2012; Committee on Educational Interventions for Children with Autism, 2001). Even when children are identified as being at risk, linking children to services can be difficult, as families are faced with navigating the complicated processes of evaluation and subsequent intervention services.

Ethnic disparities in quality of care. For those individuals that do access care, research suggests that ethnic minority families are less likely to receive high quality, evidence-based care. For example, Latino children with ASD are less likely to receive guideline concordant care than non-Latino White children with ASD on almost all quality of care indicators (Magana, Parish, Rose, Timberlake, & Swaine, 2012). In particular, parents of Latino children reported that providers were not sensitive to family values/customs and were more likely to report that providers did not make parents feel like a partner or provide enough information. Importantly, these quality indicators have been found to mediate health care utilization (Parish, Magana, Rose, Timberlake & Swaine, 2012). These findings are similar to studies of children with broader special health care needs in which caregivers of Latino children are less satisfied with the quality of care they receive compared to caregivers of White children (Coker et. al., 2010; Flores, et. al., 2005).

Addressing disparities is critical in San Diego and Imperial counties.

California has a substantial Latino population, with 38.6% of the population identified as Latino as compared to 17.4% of the population of the United States (Census Bureau, 2014). Nearly 43.8% of the population in California speaks a language other than English at home as compared to 20.9% in the United States. The large Latino population as well as the number of families who speak a language other than English leads to a large number of potentially underserved children.

The two counties served by San Diego Regional Center (SDRC), San Diego and Imperial, have a high percentage of Latino families, as 33.2% of the San Diego county population is Latino and 82% of the Imperial county population is Latino. In addition, a substantial proportion of both counties report speaking a language other than English at home (74% in Imperial county and 37.3% in San Diego county). Like other communities in California, disparities in access to early identification and service linkage have been identified as community priorities by consumers, including health care providers that have a high proportion of Latino families such as SDRC, professional groups and consumer advocacy groups. Barriers identified as part of a University of California San Diego HRSA Fellowship Training Program research project have been consistent with the literature and include 1) lack of access to bilingual providers, 2) lack of transportation, and 3) lack of resources as well as 4) living in a rural area.

Service disparities in rural areas. In addition to the challenges faced by minorities in accessing quality early intervention, families residing in rural areas face further challenges. In San Diego county, rural areas cover 3,049 square miles. In 2009, over 167,000 people resided in the rural area, representing about 5% of the county population. Maternal and child health indicators for the rural areas were different from the county overall (e.g., infant mortality was 45.5% higher than the county overall, rural area mothers were less likely to receive early prenatal care, and more likely to have a preterm baby than in the county overall). In Imperial county (the second county served under The San Diego Regional Center (SDRC), the entire county is considered rural with a total population of 179,091.

Careful examination of early intervention services in rural areas has indicated fewer available services and decreased service intensity (Wojnaroski, Perez, Guest, & O'Kelley, 2011). Though provider shortages in early intervention and special education are pervasive, this lack of trained specialists is exacerbated in rural areas and likely contributes to the lower service intensities identified in these regions (Wise, Little, Hollman, Wise, & Wang, 2010). For services that are available, early intervention providers in rural areas reported minimal use of any specific intervention programs (Stahmer, Collings, & Palinkas, 2005), indicating a likely absence of evidence based practices. Taken together, these data indicate a lack of quality early intervention available to families in rural areas, despite high levels of need (Wise et al., 2010). SDRC

An opportunity to address disparities in Southern California. Developing coordinated service access and interventions to reduce disparities for ethnic/racial minority and rural subgroups of children is critical. SDRC is well positioned to begin to address these disparities given the number of residents living in rural areas of the catchment area and the high proportion of residents who are Latino and monolingual Spanish speakers.

SDRC has started to monitor disparities within our system to prioritize addressing them. One source of tracking disparities has involved the identification of expenditures and authorized services by ethnicity and race. Latino clients in the SDRC system, along with Asian, Native American and Filipino clients, received and were authorized for less per capita purchase of services (POS) expenditures than White clients. Another means of tracking disparities was to compare clients with no POS. In this analysis, the difference across groups was significantly less, but White children were less likely to have no purchased services than other ethnic groups.

While the Latino population is only one of the groups that has been identified as receiving fewer services, within the regions served by SDRC, The U.S. Census Bureau estimates that 33% of San Diego county and 82% of Imperial county are Latino. Within San Diego county, the Latino population varies by area of the county, with the highest percentage of Latino families in the southern area of the county (60%) and Central San Diego (44%). Given the large numbers of Latino children in San Diego and Imperial counties, this population provides an appropriate group to target to decrease disparities. Given urgent calls to address ethnic disparities in the identification of developmental disabilities and linkage to quality, evidence-based intervention, we propose to specifically target Latino children. At this point, data on Latino and Spanish speaking children are not systematically collected which is problematic in gathering accurate data and clearly an area that needs to be addressed. SDRC has found that a disproportionate number of clients (30%) were identified as "other ethnicity or race", bringing into question the racial and ethnic assignments of clients.

Telehealth may improve service capacity. Recent efforts have explored the use of communication technologies to deliver specialized training over geographic distances (Dudding & Justice, 2009; Turner, 2003). These tools offer promising new models of professional preparation and service delivery that may effectively teach providers to use evidence-based practices and improve access to care for families. On-line learning can increase access to information for a greater number of people in a much more flexible format than in-person training. A nascent body of evidence indicates that web-based programs can be effectively utilized to train professionals delivering ASD services as well as deliver service to families (Hamad, Serna, Morrison, & Fleming, 2010; Wainer & Ingersoll, 2013, 2015).

Current project. This proposal aims to develop and pilot test a coordinated service model aimed to increase the number of Latino children successfully linked children served by SDRC to an evidence-based intervention that has been adapted for use in our community (Project ImPACT). The targeted population will be Latino children, including monolingual Spanish speakers and those living in rural areas of San Diego and Imperial counties. The model will be designed to be replicable for use in other Regional Centers areas across California, as well as for other underserved ethnic and racial groups.

This model will include two steps of intervention: 1) The *linkage* of the children who have screened positive to SDRC through the use of *family navigators* through partnership with local pediatric groups and existing screening programs and SDRC. 2) *Access to evidence based* intervention through the use of *telemedicine* and training of local bilingual providers through partnership with the BRIDGE Collaborative (a research-community collaborative group with the mission to increase linkage of toddlers at risk for ASD to EBPs http://bridgecollaborative.com/about).

Public Input. Public Input was received on October 11, 2016. There were 32 attendees. The two-pronged approach of providing service linkage and increasing service capacity was presented:

- The promotora model, (utilizing lay Hispanic/Latino community members who will receive specialized training of how best to access services and supports provided by the San Diego Regional Center to inform and educate their community) was described as best practice to facilitate service access.
- Training of existing service providers of the evidence based-practices was also presented as a way of increasing service capacity and leveraging technology to reach geographically difficult to serve populations.

The public did not add any additional input.

B. Strengths and Resources:

1) Existing Strengths and Resources of the System. The San Diego community is an ideal region to develop and evaluate a model of coordinated care as we have strengths in all areas of the proposed care model. SDRC has a strong and longstanding relationship with Rady Children's Hospital, San Diego (RCHSD), which serves as the "hub" in the community for services for young children. RCHSD is the only children's hospital serving San Diego and Imperial counties, holding 91% of the market share of San Diego, Imperial and Southern Riverside counties. This status has led to long term and well integrated relationships with the community agencies serving these regions, including SDRC. RCHSD's Division of Developmental Services coordinates a number of different screening and service navigation programs for young children and is a vendor with SDRC to provide developmental interventions including speech therapy, occupational therapy, developmental evaluations and naturalistic developmental behavioral interventions for children with ASD.

Service Navigation. RCHSD's Division of Developmental Services also has a successful history of securing county funding to develop and sustain community-based programs that both grow from and lead to community partnerships. Currently, there are five county funded programs in the Division of Developmental Services at RCHSD, that include First 5 funded Healthy Development Services (HDS) and Children's Care Connection (C3). These programs are designed to identify and serve children within San Diego county. The focus is on children with mild to moderate difficulties; RCHSD's leadership components of HDS are currently located in the North Coastal, North Central and South regions of San Diego. These programs are integrally involved with the local chapter of the American Academy of Pediatrics and have developed guidelines for screening and referrals in collaboration with this group. This provides an excellent resource to build from in the development of a screening and care navigation model.

Evidence-Based Intervention. The BRIDGE Collaborative (established 2007) consists of a transdisciplinary group of community providers, parents, funding agency representatives (including SDRC) and researchers (including the Co-PI, Dr. Brookman-Frazee, and Key Personnel, Dr. Rieth) working together to develop a community plan to assist families of very young children at risk for ASD and other developmental challenges. The BRIDGE Collaborative supports the use of an evidence-based, parent-implemented intervention called *Project ImPACT* for Toddlers. Project ImPACT (Improving Parents as Communication Teachers) for Toddlers is an evidence-based naturalistic developmental behavioral intervention approach designed to coach parents and caregivers of 12-24 month olds to support their children's development. The original program was developed by Brooke Ingersoll and Anna Dvortcsak (Ingersoll & Dvortscak, 2010). The evidence-based approach combines behavioral and developmental strategies to increase children's social communication and play skills during daily activities. Project ImPACT for Toddlers is an adapted version of Project ImPACT. Through the groups NIMH, Institute of Education Sciences, and Autism Speaks, research studies, providers from ten agencies serving San Diego and Imperial counties have been trained in PI for Toddlers (including one serving primarily monolingual Spanish-speaking families). Furthermore, SDRC/SDRC has vendored these agencies specifically to deliver *PI for Toddlers*. The BRIDGE Collaborative infrastructure for collaboration and training in PI is being replicated in Northern

California by Aubyn Stahmer at UC Davis. We will build on the BRIDGE Collaborative's training infrastructure and existing providers to further build community capacity to deliver EBPs.

Telehealth. RCHSD also is developing telehealth capacity and has several telehealth initiatives, including an initiative to deliver healthcare remotely to children in Imperial county. Dr. Anthony Magit is the leader of the telehealth initiative at RCHSD and believes that providing remote healthcare for children with developmental disorders to underserved areas aligns with the mission and vision of the organization. In fact, Dr. Anthony Magit recently represented RCHSD in receiving an Excellence in Telehealth Award from the California Telehealth Network. Rady Children's has HIPPA compliant telehealth equipment and videoconferencing programs that are already in use by several hospital departments to provide patient care in underserved areas.

Community Engaged Services and Implementation Research. San Diego has a rich history of conducting collaborative research between research and community stakeholders. Much of this research is conducted through the Child and Adolescent Services Research Center CASRC). CASRC, located at RCHSD, is a consortium of investigators from multiple academic institutions (RCHSD, University of California, San Diego, San Diego State University, and University of San Diego) who collaborate to conduct services and dissemination and implementation research across publicly-funded sectors of community care. Dr. Lauren Brookman Frazee (Co-PI) is the Associate Director of this center, and Dr. Sarah Rieth is also an Investigator at CASRC.

2) Gaps and Weaknesses. One of the greatest overall gaps in the system of care is the access to education, training and intervention resources in rural and impoverished areas. This gap in access is one of the primary reasons for considering telemedicine as a means of reaching areas that are remote and do not have the advantages of proximity to a major medical center. Lack of access to information and resources contributes to a lack of evidence-based care. This leads to inconsistent screening of children for disabilities during wellness visits in pediatric practices that are not part of the UC San Diego or RCHSD network or network of affiliates and also decreased access to evidence based intervention services. These are both areas we intend to address through this project.

C. Methodology:

Our first step is to link families of screened-positive children with evaluation and treatment through the use of a lay navigator. Research strongly supports the use of care <u>navigation</u> to increase family initiation of, and engagement in, services. The Project will provide specific training for children with developmental disabilities and culturally derived methods of supporting families through the service system to navigators assigned to each family. Method of engagement is a critical component, as increasing screening alone is unlikely to significantly increase linkage to treatment (Guevarra, 2013). Confusion about navigating early intervention services is a key barrier to service access (Jiminez, et. al., 2013). Likewise, a recent community needs assessment in San Diego indicated that navigating the multiple systems serving young children is a key barrier to service linkage (AAP, 2013). Navigator support has the potential to reduce disparities in access to care (Zuckerman, et. al., 2013). Use of a navigator in medical settings has been shown to promote screening, timely diagnosis and treatment of other conditions, particularly in low-income and minority communities (Freeman, et. al., 2006). The

navigator ameliorates barriers created by limited communication among agencies, and may be especially helpful in decreasing family-level barriers. Recent demonstration projects have shown the feasibility of integrating navigation services into early intervention services for children with developmental delays, supporting their utility with ASD (Roux, et. al., 2012).

Our second step will be to improve access to evidence-based treatment through a parent training model of intervention delivered by highly trained bilingual providers. Through the BRIDGE Collaborative (including representatives from SDRC, UCSD, SDSU, RCHSD, and numerous early intervention providers) we will increase the number of bilingual providers trainedin a parent-mediated, developmental-behavioral intervention, Project ImPACT (Ingersoll & Dvortscak, 2010). Project ImPACT builds on research showing that caregiver involvement is critical and that systematic blending of naturalistic behavioral and developmental approaches can address the core symptoms of ASD in infants and toddlers at risk for ASD and increase retention. Specifically, we will build on the training infrastructure of currently-funded studies testing the impact of training community therapists to deliver this intervention on community practice and child outcomes.

Project Goals and Objectives

Goal 1: Increase the number of children who are successfully linked to SDRCSDRC service through contact with a lay care navigator following a positive screen by 25% over baseline.

A. By the end of Year 1 ('16-17) increase the number of Latino children and children in rural areas who receive SDRC services by 25% over baseline.

Goal 2: Increase the number of children linked to an evidence based intervention that is culturally and linguistically sensitive by 25% over baseline.

A. By the end of Year 1 ('16-17), increase the number of Latino children and children in rural areas receiving early intervention services (either in their communities or through telehealth) from bilingual providers trained in evidence-based naturalistic developmental behavioral intervention.

Goal 3: Compare outcomes for children receiving intervention delivered via telehealth to children receiving in-person care navigation and intervention.

A. By April of 2019, analyze data comparing telehealth and in person models of intervention and determine if telehealth is as effective as in person delivered intervention.

Activities to Achieve Goal and Activities

Goal 1: Increase the number of children who are successfully linked to SDRC service through contact with a lay care navigator following a positive screen by 25% over baseline.

- A. *Identify and hire family navigators*. In partnership with the Exceptional Family Resource Center (EFRC), identify and hire lay family navigators. The intention is to recruit from families who have been successfully served through the SDRC and that live within the regions of focus. Strong partnerships exist between the UC San Diego team and the SDRC team which will facilitate recruitment of lay navigators through these agencies.
- B. *Training and Material Development for Navigators*. Training for the family navigators will integrate principles from the culturally-derived *Parents Taking Action* parent psycho-

- education intervention, developed and tested by Dr. Sandra Magana and colleagues for monolingual Spanish-speaking families. Corresponding materials, developed in Spanish for Promotora de Salud, will be adapted for use by family navigators. In addition, EFRC will assist in training family navigators in the local systems of care and local.
- C. *Translation of resources*. Access to information about resources at the local levels in the primary language of the family is also essential. Translation of all local resource information will be completed during the first phase of this project.
- D. *Enrollment of families*. At the time of initial contact with the SDRC, office staff will obtain permission for the caregivers to be contacted by the research team to provide information about the study. Participation includes the opportunity to receive service navigation support, and completion of follow up interviews over six months to track linkage to services. Family navigators will be trained and supervised by the project team and will be trained in the informed consent process.
- E. *Extraction of SDRC Data*. SDRC will continue to track data on the number of children referred to and receiving services through their program. These data will include information by zip code and numbers of Latino and Spanish speaking children and families. This will enable us to track increases in the number of children referred to and receiving services through SDRC.

Goal 2: Increase the number of children linked to an evidence based intervention that is culturally and linguistically sensitive by 25% over baseline.

- A. *Recruit bilingual intervention providers*. SDRC has a large number of vendored providers across the San Diego area and a few in Imperial county. There are also bilingual providers available through RCHSD's Autism Discovery Institute. However, there is a need for more bilingual providers in the underserved regions, particularly as we screen and identify more Latino/Spanish speaking children. During the first year of this project, we will recruit bilingual providers to be trained in Project ImPACT.
- B. *Training in telehealth technology*. We intend to train bilingual providers in the use of telehealth technology and the billing and delivery requirements. RCHSD already has the equipment and the means to deliver this intervention meeting all HIPAA and FERPA requirements and this project will start with RCHSD's bilingual clinicians already trained in evidence based practice who have access to this system. SDRC is eager to utilize telehealth with community partners through the BRIDGE Collaborative, who also have training in evidence-based practice, after ensuring access to technology that meets HIPAA requirements.
- C. *Training in evidence based practice for toddlers*. In addition to working with already trained providers in evidence based care, we will also recruit and train bilingual community based providers in an evidence based naturalistic developmental behavioral intervention model that specifically targets children under the age of three years and has evidence base for delivery

through a telehealth model (Ingersoll & Wainer, 2013). Specifically, the *Project ImPACT* intervention has been selected by the BRIDGE Collaborative and adapted for use with toddlers. Ten community-based organizations in San Diego are already contracted with San Diego Regional Center to provide *Project ImPACT for Toddlers* through SDRC. The BRIDGE Collaborative is enthusiastic about this project and has an established training and outreach model. The training will include an initial online training module and follow up coaching by Dr. Sarah Rieth (SDSU). The training will also include establishing fidelity and monitoring fidelity throughout the project.

Goal 3: Compare outcomes for children receiving intervention delivered via telehealth to children receiving in-person care navigation and intervention.

- A. *Recruitment of families*. As families are connected to the family navigator, they will be asked to participate in the project and the family navigator will describe the project and obtain informed consent.
- B. *Random assignment of conditions*. Families will be randomly assigned to one of two conditions (telehealth or in person) for the intervention arm at the time of enrollment in the study and intervention. The family navigator will be contacted by the service coordinator at SDRC to obtain consent at the time of connection to service delivery.
- C. *Measuring outcome*. Pre and post measures will be collected to determine the effectiveness of both models and if there is any difference between the two models. Patient satisfaction and time between a screen positive result and linkage to the SDRC service coordinator will be measures of outcome for the care navigation conditions. We will use the Vineland Adaptive Behavior Scales, 3rd Edition as a measure of change from pre to post intervention to assess differences between the two intervention types.

Program Monitoring

The quality process improvement process will be the model used for this project. There are hard wired and established mechanisms in place at RCHSD to ensure ongoing monitoring of project goals and objectives. RCHSD has a quality process improvement program that is held annually through the Division of Developmental Services. Dr. Corsello-Orahovats leads the project each year for the autism program and will make this project the focus of the program for the duration of the study. This program includes the RCHSD quality management team and allows for structured consultation and support with the experts in this area. The responsibility for monitoring the effectiveness of the intervention and the necessary changes that may need to be made will be shared by the co investigators of this project, Drs. Corsello Orahovats and Brookman – Frazee. Data will be collected and monitored on a monthly basis after the initial phases of recruitment and training occur. For data monitoring per project goal, see below.

Goal 1: Increase the number of children who are successfully linked to SDRC service through contact with a lay care navigator following a positive screen by 25% over baseline.

A. Each month, SDRC and RCHSD will monitor several aspects of care delivery. We will collect data monthly on the number of children receiving intervention services by SDRC region, the number of Spanish speaking families receiving services by a bilingual provider, and the length of time from initial screening to first intervention appointment. This data will be tracked using an annotated run chart, allowing us to determine if we are seeing the desired

increase in children served, children served by a bilingual provider and a decrease in the length of time from screening to first intervention appointment. Annotating the run chart allows us to track which of the interventions or events may have contributed to a data change.

Goal 2: Increase the number of children linked to an evidence based intervention that is culturally and linguistically sensitive by 25% over baseline.

- A. SDRC and RCHSD will collect data monthly on the number of children receiving intervention from bilingual providers trained in evidence-based naturalistic developmental behavioral intervention.
- B. Fidelity of implementation for those trained in and delivering the intervention model will be monitored by the BRIDGE Collaborative. Fidelity will be established at the start of intervention with families and monitored monthly throughout service delivery.

Goal 3: Compare outcomes for children receiving intervention delivered via telehealth to children receiving in-person intervention.

- A. SDRC and RCHSD will measure the effectiveness of the two family navigator conditions by comparing if there is a difference in length of time between the referral to the SDRC program and the first intervention appointment between the two conditions. While we can monitor this on a monthly basis, it will take time to gather enough cases to determine if there is a difference between the two conditions. If a clear difference emerges, with one condition far less effective than the other, we will discontinue the ineffective model or modify it to improve its effectiveness.
- B. SDRC and RCHSD will also measure changes in child functioning following completion of the intervention for a specific child. These data will be measured at the end of the intervention series, which is 24 sessions over 12 weeks. Pre and post measures will include the Vineland Adaptive Behavior Scales. In addition to monitoring intervention outcomes, we will compare the two conditions (in person or telehealth) to determine if there is a difference in desired outcome between the two conditions.

Sustainability

This entire project is designed with a focus on sustainability, replicability and scalability from identification to linkage to intervention. The majority of the funding requested is for design, monitoring, training and consultation in the development and delivery of care. The only service delivery cost that is requested are the family navigators and the mobile phones that they will need to support families using mobile technology.

The design of the study focuses on systematically reducing barriers to care described in the literature and verified through our own focus groups in the San Diego region. The plan is to utilize existing service providers and billing mechanisms for almost all aspects of the project. Pediatrician offices will conduct screening and refer families, which is an AAP standard. The delivery of intervention is also designed to be sustainable, as we would use existing billing and service delivery systems. This project will enable us to focus on telehealth delivery of care as it is much needed in rural and underserved areas. The family lay navigator is the area that requires the most exploration regarding funding for this position. We intend to research funding

mechanisms for this position as well as carefully consider efficiency, cost benefit analysis of this position if it were to be integrated into a pediatric practice, and possible billing mechanisms to ensure sustainability and replicability

Data Sharing

Data evaluating primary objectives will be provided to contracted UCSD evaluators and reported in aggregate (i.e. there will be no identifying information on specific children included). Note that most of these data are already publicly available on the State DDS website. All client level data will be collected and maintained by contracted UCSD evaluation team.

D. Work Plan:

The work plan will follow the following timeline. All components of the timeline are described in detail below.

Table 1 Work Plan Timeline

Activity	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Project Start-Up (Hiring, Database	X											
development)												
Finalize training materials (incorporating	X											
best practices in telehealth and Parents												
Taking Action)												
Extraction and monitoring of of data from		X	X	X	X	X	X	X	X			
SDRCSDRC (Goals #1 and 2)		(BL)										
Navigator Training		X										
Treatment Provider Training (Project		X										
ImPACT)												
Implement Service Navigator for Children			X	X	X	X	X	X	X	X		
Screened as At Risk (n=40 children)												
Implement EBPs (n=20 children)			X	X	X	X	X	X	X	X		
Data analysis		X	X	X	X	X	X	X	X	X	X	

Year 1 Quarter 1: Start Up and Recruitment.

Hiring of Staff. During the first quarter of this project, we will hire the research assistant and family navigators. This will be the responsibility of the PIs and will be completed by the end of the first quarter.

Project materials and processes. During the first quarter, as soon as the research coordinator is hired, the database will be developed, transfer of data workflows established, as well as the surveys implementation timelines and schedules.

Finalize training materials. Materials will be finalized in consultation with Dr. Sandy Magana and the Advisory Board.

Translation. All materials provided to families (information about the research study, information about each step in the process, and State and local resources) will be available in both English and Spanish. When not already available, English materials will be translated and back translated by a certified translator. Furthermore, it will be reviewed by bilingual/bicultural providers and parents from the BRIDGE collaborative as was the process for the Spanish version of Project ImPACT for Toddlers (one of the EBPs being implemented through SDRC in San Diego and Imperial counties).

Recruitment of Intervention Providers. One of the first goals of this project will involve recruitment interventionists for enrollment, which will be a focus in the first quarter following funding. In partnership with the BRIDGE collaborative, we will recruit providers already trained in the evidence based parent coaching model (Project ImPACT) to deliver the intervention using telehealth. In addition, bilingual providers who have not yet been trained in the evidence based intervention model will be recruited to be trained to deliver the intervention. We intend to recruit at least five bilingual providers.

Year 1 Quarter 2: Baseline assessment and training.

Collection of baseline data. Baseline data will be collected for the Goals 1 (children linked to SDRC) and 2 (children linked to evidence based intervention).

Navigator Training (Service Navigation). Training for the navigators will be developed in collaboration with Dr. Sandy Magana.

Interventionist Training (Evidence-based Intervention). In partnership with the BRIDGE collaborative, those providers already trained in the evidence based parent coaching model (Project ImPACT) will be trained to deliver the intervention using telehealth. In addition, bilingual providers who have not yet been trained in the evidence based intervention model will be trained to deliver the intervention. The training for this model training involves a combination of didactic, coaching/performance feedback, and fidelity monitoring. There are agency trainers at all 10 of the organizations who have been trained by the BRIDGE collaborative in use of this model with toddlers. BRIDGE will provide technical assistant to the agency trainers as they train new staff.

Year 1 Quarters 3-4: Implementation of screening, care navigation, and evidence based intervention.

Care navigation implementation. Following training, care navigators will begin providing the navigation intervention to families referred from participating pediatricians (i.e. children identified at risk during initial screening). Navigation will include immediately contacting families to facilitate their linkage to SDRC. Navigators will use components adapted from Dr. Magana's Promotoras de Salud "Parents Taking Action" Psycho-educational intervention to provide families information about the ASD assessment process and resources. Additionally, they will provide individualized support to help link the family to SDRCSDRC and EBP early intervention services. Navigation will be provided in-person or via telehealth (see random assignment below).

Evidence based intervention implementation. Project ImPACT for toddlers is already a model of intervention already vendored through SDRC in 10 agencies. This evidence based parent coaching naturalistic developmental behavioral intervention that occurs in 24 sessions delivered

over 12 weeks. Intervention will be provided in – person or via telehealth (see random assignment below).

Family random assignment and consent for intervention. Approximately 40 families will be recruited to participate in the evaluation phase of the project. Once a referral is received by the SDRC intake coordinator and determined eligible for services, the family will be connected with a family navigator. The outcomes team will randomize the family to one of two service conditions (in-person or telehealth) for the intervention. Approximately 20 families will be recruited to participate in the intervention phase of this project.

Data monitoring and adaptation of workflows and interventions. The project PIs and SDRC designee will meet and review data monthly with the research team and lay navigators. Each month throughout the project, a determination will be made as to whether there is progress made toward the goal and whether there need to be modifications made to the workflows and interventions. Modifications will be made accordingly.

Year 3

Data analysis and synthesis: Data on all goals, including the differences between in person and telehealth delivered interventions will be analyzed and readied for presentation.

Dissemination. The Executive Director of the San Diego Regional Center will disseminate the data, findings and manual at the State Regional Center meetings. The Manager of the Early Start Program will disseminate the findings at the statewide SDRC meetings. Results will also be disseminated more broadly through CAPTAIN, a multidisciplinary agency network with over 400 members, representing 87% of the California Special Education Local Plan Areas (SELPAs), Regional Centers, Diagnostic Centers and Family Resource Centers.

E. Resolution of Challenges:

Recruitment of Children and Families. Recruiting children and families to participate in intervention studies can be time intensive and challenging. Rady Children's has a far reach, as it has 91% of the market share across San Diego, Southern Riverside and Imperial counties. The large catchment area results in relationships with a large number of pediatric practices that refer to Rady Children's for specialty medical services. We plan to leverage this relationship to identify Latino families willing to participate in this project. In addition, we have a team very experienced in recruitment, as we have recruited over 200 children in genetics research studies and Dr. Brookman Frazee recently received a supplement to an NIH funded project, given the high number of minority and underserved children she successfully recruited into her intervention study.

Data Sharing and Privacy Requirements. Projects that work across sites can lead to challenges with collecting and sharing data. We intend to manage this by using aggregate and readily available data when possible (such as stats and facts reported on the DDS website regarding SDRC active cases). SDRC is also committed to continuing to collect additional data regarding ethnicity and primary language, and can report by zip code, given the focus at the state level on

reducing disparities in healthcare. This data can also be reported in aggregate as the other Regional Center data. We will have the SDRC coordinators consent the families at the time of contact and this will include data sharing across providers and the project team. The research team will be responsible for collecting and entering individual client data for families who agree to participate in the project.

Sustainability. Another goal of this project will be to ensure sustainability, which can be a challenge with new services. We will explore funding sources for the family navigator as well as billing mechanisms for intervention in order to ensure that we have created a sustainable model.

F. Evaluation and Technical Support Capacity:

Overall Program Purpose/Objectives

The ultimate goal of this project is to increase the number of Latino children identified, referred, and connected to SDRC services prior to their third birthday, and to decrease the disparities in service access and use in Latino families across San Diego and Imperial counties. We also intend to develop a model that can be adapted for use with other ethnic populations who are experiencing disparities in service access and use. In order to achieve this goal, the focus of this project during the first 2 ½ years will be to develop and test a model of early identification and linkage to evidence based care within San Diego and Imperial counties.

Proposed Project Goals/Objectives

The project goals focus on impacting the number of children effectively linked with SDRC evidence based intervention. To ensure impact, we will focus on the areas within San Diego and Imperial counties with the highest Latino and Spanish speaking populations. We will collect data at three levels 1) Aggregate, de-identified data from SDRC, including DDS statistics and per capita POS authorizations, expenditures by ethnicity and race 2) Child level data for children and families who receive evidence based care with a participating provider.

Data Collection/Outcomes

Data Collection. Data collection will occur at two levels, from the following sources. Data collection will occur at the aggregate level by SDRC. Publicly available data will be accessed from the State DDS system websites when possible (e.g. Stats and Facts on the DDS website). In addition, IRB approval through the joint UCSD and RCHSD IRB will allow for the collection of client level data after families have been recruited to participate in the project by the research coordinator, SDRC coordinator or family navigator. IRB approval will also include retrospective record review for the purpose of the project by the project staff.

Goal 1: Increase the number of children who are successfully linked to SDRC service through contact with a lay care navigator by 25% over baseline.

Monthly data collection and annotated run charts will enable us to determine if specific interventions have had a desired effect. Our outcome measure for this goal will be the percentage of children referred to the SDRC program effectively linked with an intervention. These data will be gathered monthly from the SDRC program. The effectiveness of the family navigator is also an important component of ensuring effective linkage. For this reason, we will use a measure of fidelity of implementation of the family navigation strategies. Interviewing SDRC care

coordinators and family navigators will be conducted as well as shadowing. If we do not see the desired increases in children linked to intervention through SDRC, issues will be identified and addressed as guided by our data. Balancing measures will again be incorporated to ensure that there are not unintended negative consequences of our intervention. To this end, we intend to look at staff retention of the lay navigator position. In addition, patient satisfaction will be measured monthly to ensure that families continue to feel satisfied and that there is no drop in patient satisfaction scores following intervention. We will adapt the Rady Children's patient satisfaction questionnaire for this purpose and include specific questions related to the effectiveness of the service model in addressing common barriers to care.

Goal 2: Increase the number of children linked to an evidence based intervention that is culturally and linguistically sensitive by 25% over baseline.

As with Goal 1, monthly data collection and annotated run charts will enable us to determine if specific interventions have had a desired effect. Our outcome measure for this goal will be the number of children who have screened positive who are connected to evidence based intervention. These data will be collected by the SDRC program on a client level for those children who have agreed to participate in the research project. One of the factors that will contribute to the ability for children to access evidence based care is that there are sufficient bilingual providers trained in evidence based models of intervention. For this reason, the number of vendored bilingual SDRC providers trained in evidence based care for young children will be tracked monthly as a process measure. The balancing measures for this goal will include the number of children who complete the intervention series or remain in intervention if the goals continue and patient satisfaction scores. Patient satisfaction will be collected at the end of the intervention series or transition from the SDRC program by the SDRC care coordinators under the direction of the SDRC managers.

Table 2: Quality Process Improvement Measurement of Goals

Goal	Outcome	Process	Balancing
Goal 1: Increase the number of children who are successfully linked to SDRC service following a positive screen by 25% over baseline.	 Percent of children who are eligible for SDRC services that are successfully linked to intervention Length of time between receipt of referral and first scheduled intervention appointment 	 Percent of children linked to service navigator Adherence to workflow that includes care navigator Navigator fidelity 	 Patient satisfaction Staff retention
Goal 2: Increase the	Number of	Number of	Patient
number of children	children enrolled	providers trained	engagement
< 3 years linked to	in an evidence	in evidence based	(number of
an evidence based	based	care	sessions attended)

intervention that is	intervention	Percent of
culturally and		children who
linguistically		complete the
sensitive by 25% over		intervention
baseline.		episode

Goal 3: Compare outcomes for children receiving intervention delivered via telehealth to children receiving in-person intervention.

The third goal is an embedded research goal, which will evaluate the parent coaching model of intervention delivered in person as compared to delivered via telehealth. To test this hypothesis, families will be enrolled in this arm of the project as a research subject. Each participant will be randomly assigned to telehealth or in person delivered interventions. For the parent coaching model of intervention repeated measures ANOVA will be used, to compare Vineland scores at pre and post intervention and patient engagement based on the number of sessions attended for the two conditions (telehealth vs. in person).

Contractors:

Principal Investigator: Dr. Christina Corsello Orahovats is the Clinical Director of the Autism Discovery Institute which is within the Developmental Services Division at RCHSD. Within this role, she has been responsible for clinic operations and is very familiar with quality process improvement model, having been involved in quality process improvement courses led by the Quality Management team at RCHSD for the past 10 years. She has received extensive training in this model through the Leadership Academy which she attended at the suggestion and referral of the CEO of the hospital, who recognized her leadership skills. She has developed close working relationships with the Chief Safety Officer of the hospital, who has provided consultation and support during quality improvement projects through both the Leadership Academy and the Developmental Services division wide courses.

Dr. Corsello Orahovats also has an in-depth understanding of the revenue cycle, including coding and billing as well as health plan requirements. As the clinical director of an autism program located within a hospital during the time that the laws in California changed to allow billing health plans for applied behavior analysis, she had to work closely with the hospital coding and billing department as well as with the health plans to ensure compliance with requirements. This has given her a solid basis in billing related issues as well as led to collaborations with the revenue cycle department, which will be critical as barriers related to billing for intervention for Latino and low income families are considered.

In addition, Dr. Corsello Orahovats is the Clinical Director for the Developmental Evaluation Clinic, an evaluation clinic at RCHSD specializing in developmental evaluations for young children. Approximately 50% of the children seen through this clinic are funded through MediCal as a part of an Early Periodic Screening and Development and Training grant and contract. Dr. Corsello Orahovats participates in quarterly managers meetings with the county as a part of this contract. This clinic sees many bilingual and Spanish speaking children for initial evaluations and has three bilingual psychologists on staff.

In addition to her administrative background, Dr. Corsello Orahovats also has a strong background in diagnosis and assessment in autism spectrum disorders, having worked closely with Dr. Catherine Lord, the developer and author of the Autism Diagnostic Observation Schedule (ADOS: Lord, et. al., 2000), a measure considered the gold standard for diagnosis for research and clinical purposes. She continues to see children clinically for evaluations to determine if the children meet criteria for a diagnosis of an autism spectrum disorders. She also has a background in research and is the author of several peer reviewed publications, including papers on screening and chapters on diagnostic measures.

Dr. Corsello Orahovats has extensive experience, not only in providing clinical care, but also in developing programs and launching and completing quality process improvement projects. She has the connections within the departments of the hospital, including quality management and revenue cycle, as well as with community agencies to successfully carry out this project.

Dr. Lauren Brookman Frazee.

Dr. Brookman-Frazee is an Associate Professor of Psychiatry at the University of California, San Diego, Associate Director of the Child & Adolescent Services Research Center (CASRC) and Research and Training Director at the Autism Discovery Institute at RCHSD-San Diego. Her expertise is in community partnered services and implementation research. Specifically, she conducts research on methods to improve community services for individuals with autism spectrum disorder by characterizing routine care and through the development, adaptation, and implementation of evidence-based interventions for delivery in routine care settings, including early intervention services provide by California SDRC. She has extensive experience administering large grants, developing and studying interventions delivered in community settings, and developing and studying research-community partnerships. Dr. Brookman-Frazee is currently the PI of a large-scale. NIMH-funded R01 study testing the effectiveness of a mental health intervention for children with ASD (AIM HI) delivered in publicly-funded clinic and school-based mental health programs in LA and San Diego counties and characterizing implementation and sustainment process and outcomes. She was recently awarded supplemental funding to examine methods to reduce disparities in delivering evidence-based interventions to children with ASD. Furthermore, she is PI (Multiple PI with A Lau) of an R01 study examining the sustainment of multiple evidence-based practice fiscally mandated for delivery in child mental health services in LA county. This study involves examining inner context (organizational and provider characteristics) associated with sustained implementation. Lastly, she is co-PI and site PI on the BRIDGE project (PI: Stahmer), funded by Autism Speaks and U.S. Department of Education Institute for Education Sciences. This project uses a researchcommunity partnership approach to adapt and test the community implementation of evidencebased intervention for very young children showing risk for ASD. The proposed project builds directly on the BRIDGE project.

Dr. Brookman Frazee and Dr. Corsello Orahovats have been working together for the past 10 years and co-lead the Autism Discovery Institute. Dr. Brookman Frazee is ideally suited to colead this project given her expertise and success in services research, recruitment of underserved populations and her early intervention, and adapting and implementing evidence based practice in community settings.

Trainers

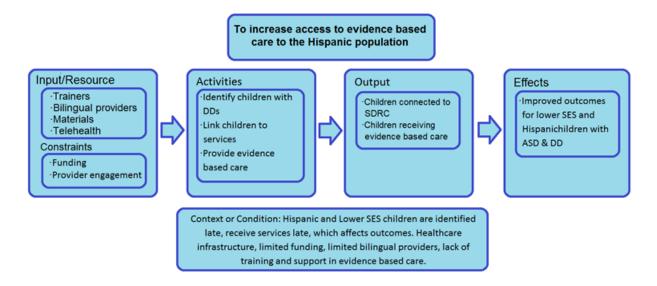
Dr. Sarah Rieth is an Assistant Professor in the Department of Child and Family Development at San Diego State University and an Investigator at the Child and Adolescent Services Research Center. Her research focuses on translating evidence-based practices for children and families with ASD to community settings, with a particular emphasis on adapting interventions for new populations and settings as well as sustainable provider training and support models. She is a coinvestigator on the BRIDGE Project (PI: Stahmer), along with Dr. Brookman-Frazee, and has served as the lead clinical trainer for all the San Diego agencies that have received training in Project ImPACT for Toddlers as well as supervising the effectiveness research. She is also involved in a randomized trial of a school-based intervention for students with ASD that involves extensive teacher training and coaching in classroom settings. Dr. Rieth has a successful history of working collaboratively with community stakeholders in multiple contexts (e.g., early intervention service system, education system) as well as conducting rigorous community-based research to ensure the fit of training and service models with the community.

Dr. Sandra Magana. Dr. Magaña is a Professor in the Department of Disability and Human Development at the University of Illinois Chicago. Dr. Magaña's research focus is on the cultural context of families who care for persons with disabilities and mental illness and the experiences of parents who have disabilities. More recently, her research has focused on health disparities for minority caregivers and diagnosis and treatment disparities for Latino and Black children with an autism spectrum disorder; and on interventions to reduce health and service disparities. She has developed and tested a culturally-derived lay health worker parent psychoeducation intervention for families of children with ASD and is a collaborator on Dr. Brookman-Frazee's AIM HI study. Dr. Magana will consult on this project by assisting the team in the development of the lay navigator training model by applying components of her the Promotora de Salud model.

Program Logic Model

This model considers the barriers to care as well as the resources necessary to address them. Within each goal, we have identified and outlined the activities necessary to achieve the goals, the result that we hope to achieve with the ultimate goal of improving the outcomes of Latino children with developmental disabilities (see Figure 1).

Figure 1 Program Logic Model



F. Contracting Organizational Information:

Drs. Corsello - Orahovats and Brookman-Frazee are both faculty at UC San Diego who are located at RCHSD San Diego, the pediatric teaching hospital for UC San Diego. RCHSD, with 441 beds is the largest children's hospital in California, serving a community of more than three million people, 28% of whom are below 18 years of age. RCHSD is the only children's hospital in the San Diego area and has 91% of the market share in San Diego, Imperial and Southern Riverside counties. Developmental Services is one of the largest divisions in the hospital, and includes developmental services (speech therapy, occupational therapy, physical therapy, and audiology), mental health services for young children (KidSTART, The Developmental Evaluation Clinic and The Autism Discovery Institute), as well as large county grant funded community programs (Children's Care Connection, Healthy Development Services, Developmental Screening and Enhancement Program). Two of these grant funded programs provide screening and care coordination services and work closely with community pediatric practices and the AAP - CA3. RCHSD also has a Quality Management program that provides support and training in quality process improvement projects. There is an organizational initiative to increase services using telehealth. RCHSD has an electronic medical record that connects the physicians and providers working at the hospital as well as pediatricians in the community.

The Child and Adolescent Services Research Center (CASRC), located at RCHSD, and the University of California San Diego, Department of Psychiatry will provide the overall support structure for the proposed research activities; including the computer infrastructure, all statistical software, access to electronic libraries, office space and administrative support. CASRC is embedded in the community and has a long standing relationship with mental health and child welfare and community based organizations that provide services to children throughout San Diego county.

CASRC is a consortium of investigators from multiple academic institutions (RCHSD San Diego, University of California, San Diego, San Diego State University, and University of San Diego) who collaborate to conduct services and dissemination and implementation research across publicly-funded sectors of community care (Mental Health, Developmental Disability, Education, Vocational, Substance Abuse, Primary Care, Child Welfare). CASRC was established in 1989 by founder Dr. John Landsverk and is currently directed by Dr. Greg Aarons with associate director, Dr. Lauren Brookman-Frazee. To date, CASRC has received over \$122 million dollars to conduct research and program evaluation. Target populations include individuals with autism spectrum disorders, mental health disorders, substance abuse disorders, trauma and child maltreatment histories, early developmental problems, HIV. Furthermore, interventions studied target system, organization, provider and individual levels.

Institutional Review Board: UC San Diego and RCHSD, have created a single submission/dual tracking process for IRB applications. Both UC San Diego and RCHSD salaried faculty, staff, and students submit a single set of application, materials and protocol-related documents, and receive IRB reviews from both institutions. These services apply to the initial submission of a new project, and to the ongoing review and monitoring by both institutions that is mandated by federal regulations and institutional policy. San Diego State University and the University of San Diego have recently implemented a web-based IRB application process as well. Furthermore, SDSU and UC San Diego have a cooperative agreement and process that allows the SDSU and UC San Diego IRBs to rely on each other for review and approval of studies being conducted jointly by SDSU and UCSD. Similarly, all UC campuses share an IRB reliance registry to reduce burden for investigators, IRB member and staff and facilitate multi-campus collaboration.

University of California, San Diego, Department of Psychiatry

Since its inception in 1969, the Department of Psychiatry at the University of California, San Diego has developed into one of the most innovative and productive academic departments of psychiatry in the country. The guiding principle has been that the educational and research programs of a psychiatry department must be at the cutting edge and encompass and integrate the most current innovations in the field with those approaches from the past which have proven to be valid and effective. The department has a strong commitment to the dynamic understanding of an individual's current social context and feelings, and past behaviors and experiences. They have created one of the best available integrations of the biopsychosocial approaches to understanding normal and abnormal human behavior. By design, a rich diversity of scientific and clinical strategies are represented within the department, but the core organizing ethic of the educational and training programs is a profound commitment to the patients' well-being. It is their conviction that clinical psychiatry can only be learned in the context of meaningful interaction and contact with patients. The Residency Training Program is developmental in nature, appropriately challenging the residents at each level as they move from intensively supervised beginners to autonomous, confident, skilled clinicians and colleagues at graduation. The training occurs within the department's ambiance of collegiality, enthusiasm, openness of communication, intellectual and scientific rigor, and spirit of inquiry, which characterize the highly productive and energetic faculty. The UCSD faculty represents a virtual who's who of world-class basic and clinical scientists and clinicians, all of whom are available and participate

in the residents training and experiences. All Center investigators/staff affiliated with UCSD have their offices at CASRC and share in all of CASRC's resources.

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Budget Justification

SDRC Grant Lead and Monitor will be Ron Plotkin, Ph.D., Special Projects Manager. No money is requested to monitor the grant progress and outcomes.

Contractors

Name	Title, Institution	Project Role	Amount Requested in Year 1*	
Outcomes				
C. Corsello Orahovats, Ph.D. 12.5% FTE	Associate Professor of Psychiatry, UC San Diego	Lead Contractor	\$23,257 total	
L. Brookman –Frazee, Ph.D. 5% FTE	Associate Professor of Psychiatry, UC San Diego	Co-Lead Contractor	\$11,429 total	
TBN 100% FTE	UC San Diego	Project Coordinator	\$67,011 total	
Trainers				
S. Reith, Ph.D., 9.38% FTE	Assistant Professor of Child and Family Studies, SDSU	Project ImPACT Trainer	\$15,036 total	
Sandra Magana, Ph.D.	Professor, Disability and Human Development, University of Illinois, Chicago,	Family Navigator Trainer	\$5000 (Years 1 and 2 only)	
Services Providers				
TBN 40% FTE	UC San Diego	Family Navigator	\$22,269 total	
TBN 40% FTE	UC San Diego	Family Navigator	\$22,269 total	
TBN 40% FTE	UC San Diego	Family Navigator	\$22,269 total	

^{*} The amount requested in subsequent budget years will increase by 3% annually due to the projected increases in the annual salary rates for each individual listed. The effort levels remain the same throughout the project. Salaries and applicable fringe benefits have been included in the total.

Materials

Laptops (\$3600 in year 1 only). Three laptops will be purchased, one for each of the family navigators and one for the project coordinator. Laptops will be used for data collection and for documentation purposes.

Protocols/measures (\$1000 in year 1 only). We have allocated \$1000 for purchase of the two Vineland Manuals and protocols for pre and post evaluation of intervention.

Travel

Mileage (\$3000 each year; \$9000 total). We have allocated \$3000 in mileage for travel of Dr. Sarah Reith to travel to and from training locations and for lay navigators to travel to work with families in vivo. We anticipate a total of 5,556 miles annually at a current mileage rate is \$.54 a mile.

Conferences (\$2000 each year; \$6000 total). We have allocated \$2000 for Dr. Lauren Brookman Frazee or Dr. Christina Corsello Orahovats to present at IMFAR. The next IMFAR conference will be held in San Francisco

Other Project Expenses

Translation (\$3000 in year 1, \$3500 in year 2, and \$1000 in year 3; \$7500 total). We have budgeted \$7500 across the three years of the grant period to ensure that resource information was translated and available in Spanish. This includes websites, brochures and educational materials.

Participant Compensation (\$4500 in year 1, \$5000 in year 2; 4500 in year 3;\$14000 total). Participant compensation is budgeted to provide to families and providers that participate in focus group meetings, enroll in the family navigator service and enroll in the intervention comparison study.

Project ImPACT Web-based Training (\$1500 per year; \$4500 total). We have budgeted \$4500 to maintain the Project ImPACT online training modules to be accessed by the bilingual providers who are being trained in this evidence-based intervention.

Indirect Costs

UC San Diego's indirect costs are at 15% and we request a total of \$91,189 to cover this cost, which is broken down as \$32,412 in year 1, \$29,712 in year 2, and \$29,065 in year 3.

Total Costs Requested

The total requested for contracted project and services are \$744,057, which includes direct and indirect costs - \$248,489 in year 1, \$248,729 in year 2, and \$246,839 in year 3.